

REMARKS

Claims 49 through 60 were pending in this application. Claims 49, 51 through 53, 56, and 59 are amended herein. Upon entry of the present Amendment, claims 49 through 60 will be pending in this application and are presented herein for reconsideration.

Claims 49 and 56 are amended to recite a “calcium agent suitable for absorption by a mammal.” Support for these amendments can be found throughout the application as originally filed, for example, at least at page 6, lines 5 through 8. Claims 51 and 52 have been amended to recite appropriate dependencies. Support for these amendments can be found throughout the application as originally filed. Claim 53 has been amended to recite “the amount effective to induce a bone strengthening effect in a mammal is between 10mg to 2500mg of degraded collagen per day.” Support for this amendment can be found throughout the application as originally filed, for example, at least at page 6, lines 10 through 12. Claims 53 and 59 are amended to correct typographical errors. Applicants respectfully submit that no new matter is introduced by these amendments.

Rejection Under 35 U.S.C. § 102(b)

Claims 49 through 52, and 56 through 60 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cioca et al. (U.S. Patent No. 4,285,986, hereinafter “Cioca”), and Garantol-Gesellschaft, Ltd. (DE 178343, abstract only, hereinafter “Garantol-Gesellschaft”). Applicants traverse these rejections.

For anticipation under 35 U.S.C. § 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. MPEP 706.02. Applicants submit that the

Office action's rejection is improper because neither Cioca nor Garantol-Gesellschaft disclose every aspect of Applicants' invention as claimed herein.

Firstly, the Office action specifically rejects claim 49, suggesting that Cioca teaches a composition of hydrolyzed collagen peptides, calcium, and vitamin D₃. However, claim 49, as amended, and those claims depending therefrom (claims 50 through 60), recite a composition for strengthening bone comprising "a calcium agent suitable for absorption by a mammal." Thus, the calcium agent in the composition must be readily absorbable by the mammalian subject. However, the only calcium containing micronutrients taught by Cioca as being suitable for addition to Cioca's collagen preparation are calcium phosphates, (i.e. calcium phosphate, calcium diphosphate) (See Col. 3, line 29, Col. 4, lines 46 through 48). As shown in the evidence submitted by the Applicants' in the Amendment and Response of September 9, 2004, calcium phosphates are irreversibly insoluble. This prevents passive absorption by the ileum. (See *Journal of the American College of Nutrition*, Vol. 19, No. 2, 119S-136S (2000) at 121S, submitted by the Applicants on September 9, 2004). Furthermore, the Office action suggests that the fact that "phosphates...do not have good absorptivity...would apply to the current rejection," but for the fact that claim 49 "[did] not state that a particular type of calcium should be used or a specific calcium salt should be used for a specific purpose." Consequently, Applicants have amended claim 49 to clarify that the calcium agent comprising the bone strengthening compound must be one "suitable for absorption." As such, Applicants submit that because the calcium phosphate taught by Cioca is not suitable for absorption by a mammal, Cioca does not teach a composition with all the limitations of amended claim 49, and is therefore an improper reference under 35 U.S.C. § 102(b). In light of the foregoing reasons, Applicants respectfully submit that

the rejection of independent claim 49 and dependent claims 50-60 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

Furthermore, Applicants submit that Cioca is not relevant to the claimed invention because Cioca does not teach or suggest a composition that induces a bone strengthening effect. In fact, Cioca merely teaches that “the use of oligopeptides in connection with the bulk and micronutrients provides for reduced mortality of pigs during the weaning stage and provides an increased utilization of food by way of weight gain and health” (Col. 3, lines 40 through 45). However, the Office action suggests that such an argument is irrelevant to the claims’ patentability because a limitation in the preamble is generally not accorded any patentable weight. However, independent claim 49, from which claims 50 through 60 depend, recites “a composition for strengthening bone...wherein said composition is suitable for oral administration in an amount effective to induce a bone strengthening effect.” This limitation, while being mentioned in the preamble is also recited in the body of claim. Therefore, Applicants’ argue that because Cioca does not teach that the composition is effective at inducing a bone strengthening effect, all limitations of independent claim 49 are not met, and therefore Cioca is an improper reference under 35 U.S.C. § 102(b). In light of the foregoing reasons, Applicants respectfully submit that the rejection of independent claim 49 and dependent claims 50 through 60 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

The Office action specifically rejects claim 56, as being anticipated by Cioca, suggesting that egg shell derived calcium listed in claim 56, as evidenced by Garantol-Gesellschaft, includes *inter alia* calcium phosphate. However, claim 56 has been amended to recite a “calcium agent suitable for absorption by a mammal.” For the reasons discussed *supra*, calcium phosphate is not suitable for absorption by a mammal. Therefore, because Cioca, as evidence by Garantol-

Gesellschaft does not teach or suggest all of the claimed limitations, it is an improper reference under 35 U.S.C. § 102(b). For these reasons, applicants respectfully request that the rejection of claim 56 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

The Office action specifically rejects dependent claims 50 through 51 and 57 through 58, as being anticipated by Cioca, suggesting that the claimed products are not distinctly patentable because the patentability of product by process claims is based on the product itself. Applicants traverse the rejection. However, Applicants believe the Office action's argument is moot in light of the amendment to claim 49, on which claims 50-51 and 57-58 depend, and in consideration of arguments made in support of the amendment to claim 49 *supra*. Therefore, Applicants respectfully request that the rejection of claims 50-51 and 57-58 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

Rejections under 35 U.S.C. § 103(a)

Claims 53 through 55 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentably obvious over U.S. Patent 4,285,986 (Cioca et al., hereinafter "Cioca"). Applicants respectfully traverse the rejection. The Office action suggests that the difference between Cioca and the Applicant's application is that Cioca does not disclose the concentration of collagen and the ratio of collagen:calcium as claimed by the Applicants. However, the Office action suggests that there is a motivation to use the Cioca reference to determine an optimum set of ranges because the "normal desire of scientists or artisans [is] to improve upon what is already generally known." Conversely, applicants submit that there is in fact no motivation for one skilled in the art to look to Cioca to optimize the ranges of components in a composition for strengthening bone. Firstly, as discussed *supra*, Cioca does not teach or suggest that his composition can be used for strengthening bone. Thus, if a skilled artisan intended to optimize components in a

composition for strengthening bone, she would have no motivation to look to art outside the realm of bone strengthening. Furthermore, even if there were a motivation to look to Cioca to optimize the ratios of components, because rejected claims 53 through 55 are dependent on independent claim 49, Cioca must provide the skilled artisan with motivation to prepare a composition according to all limitations of the claim, including “a calcium agent suitable for absorption by a mammal.” Considering that Cioca neither teaches nor suggests a calcium agent suitable for absorption, as discussed *supra*, a skilled artisan could not, based on the teachings of Cioca alone, arrive at a composition that meets all the limitations of amended claim 49 from which claims 53 through 55 depend. Consequently, Applicants submit that Cioca is an improper reference under 35 U.S.C. § 103(a) and respectfully request that the rejection of claims 53 through 55 be reconsidered and withdrawn.

In addition, even if there were a motivation to optimize the components of Applicants’ composition based on the teachings of Cioca, Applicants respectfully reject the Office action’s suggestion that the claimed ratios are in fact “optimum or workable ranges [determined] by routine experimentation.” Rather, Applicants respectfully submit that the claimed ratios are not merely an arbitrarily selected range, but rather the preferred ranges determined in practice and exemplified in the specification. Applicants respectfully submit that these claims are patentable because they are in fact critical to the effectiveness of Applicants’ bone strengthening compound. As stated in the Office action, “differences in concentration will...support the patentability of subject matter...[when] there is evidence indicating such a concentration...is critical.” As exemplified in the specification, such ratios were determined to be essential to the effectiveness of the compound in strengthening bone. For example, at page 15, lines 1-3, the specification states that a “combination of 0.5-5.0 weight part of a fraction containing collagen with 1 weight

part of calcium was found to be effective.” Consequently, Applicant submit that the specification does not teach a mere optimization, but a range that is critical to ensure effective bone strengthening. Therefore, Applicants respectfully request that this ground of rejection of claims 53 through 55 under 35 U.S.C § 103(a) be reconsidered and withdrawn.

CONCLUSION

Claims 49-50 were pending in the Application. Claims 49, 51-53, 56, and 59 are amended. Applicants respectfully submit that no new matter is introduced by the present Amendment.

Applicants request that the Examiner reconsider the application in light of the foregoing Amendment and Response, and respectfully submit that the claims are in condition for allowance. If the Examiner believes a telephonic interview would expedite the favorable prosecution of this application, the undersigned attorney would welcome the opportunity to discuss any outstanding issues, and to work with the Examiner toward placing the application in a condition for allowance.

Respectfully submitted,

Brian Fairchild
Brian Fairchild (48,645)
on behalf of

Christine C. Vito

Christine C. Vito
Attorney for the Applicants
Kirkpatrick & Lockhart Nicholson
Graham LLP
75 State Street
Boston, Massachusetts 02109-1808

Date: February 14, 2005
Reg. No. 39,061

Tel. No.: (617) 261-3150
Fax No.: (617) 261-3175